

Drugs recently approved or pending approval

RELENZA

The United States Food and Drug Administration approved marketing of Relenza (zanamivir for inhalation) by Glaxo Wellcome (Research Triangle Park, NC). Relenza is indicated for the treatment of uncomplicated acute illness caused by influenza A and B viruses in adults and adolescents age 12 years or older who have been symptomatic for no more than 2 days. Drug efficacy was evaluated in several placebo-controlled studies involving patients age 12 years and older. Patients with confirmed influenza ($n = 1164$), 89% with influenza A and 11% with influenza B, were randomized to Relenza or placebo (inhaled lactose vehicle). Definition of improvement in major influenza symptoms included absence of fever and self-assessment of "none" or "mild" for headache, myalgia, cough, and sore throat. Two studies involving more than 600 patients suggested up to a 1-day shortening of median time to the defined improvement in symptoms in the Relenza arms compared with the placebo arms; however, these studies did not demonstrate statistical significance. Another study involving 321 patients demonstrated a 1.5-day shortening in median time to symptom improvement in the Relenza arm compared with the placebo arm. Adverse reactions associated with Relenza may include nasal signs and symptoms, nausea, diarrhea, and sinusitis. The recommended dose of Relenza is two oral inhalations (one 5-mg blister per inhalation for a total dose of 10 mg) twice daily, approximately 12 hours apart, for 5 days.



KOATE-DVI

Bayer Corporation (Pittsburgh, PA) received approval to market Koate-DVI (antihemophilic factor [human]). Koate-DVI is indicated for the treatment of hemophilia A in which a demonstrated deficiency of activity of the plasma clotting factor, factor VIII, exists. Koate-DVI provides a means of temporarily replacing the missing clotting factor in order to control or prevent bleeding episodes or in order to perform surgery on patients with hemophilia. A double viral inactivation (DVI) process to inactivate non-lipid enveloped viruses and lipid enveloped viruses increases the purity of the factor VIII. Efficacy of Koate-DVI was measured in a two-stage clinical study involving patients with hemophilia A who had been treated previously with other plasma-derived antihemophilic factor concentrates. In the first stage, patients ($n = 19$) were treated with Koate-DVI. Statistical comparisons demonstrated that Koate-DVI was a bioequivalent to the unheated product, Koate-HP. The incre-

mental *in vivo* recovery 10 minutes after infusion of Koate-DVI was 1.9% IU/kg compared with 1.82% IU/kg for Koate-HP. Mean biologic half-life was 16.12 hours for Koate-DVI compared with 16.13 hours for Koate-HP. In the study's second stage, patients received Koate-DVI home therapy treatments for 6 months with a median of 54 days (range, 24 to 93 days). No evidence of inhibitor formation was demonstrated. Possible adverse reactions associated with Koate-DVI are mild and include tingling in the arm, ear, and face, blurred vision, headache, nausea, and stomach ache. The dosage of Koate-DVI necessary to achieve hemostasis must be individualized based on the needs of the patient, the severity of the patient's deficiency, the severity of bleeding, the presence of inhibitors, and the desired factor VIII level.

ACTOS

The Food and Drug Administration granted approval to Takeda Pharmaceuticals America (Lincolnshire, IL) and Eli Lilly (Indianapolis, IN) to market Actos (pioglitazone hydrochloride). Actos is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Actos is indicated as monotherapy or in combination with a sulfonylurea, metformin, or insulin when diet and exercise plus Actos does not result in adequate glycemic control. Efficacy of Actos was evaluated in six double-blind placebo-controlled studies. In one study that evaluated Actos as monotherapy, patients ($n = 408$) with type 2 diabetes were randomized to receive Actos (7.5, 15, 30, or 45 mg) or placebo once daily. Improvement in hemoglobin A_{1c} (HbA_{1c}) and fasting blood glucose (FBG) levels were the study's primary endpoints. In therapy-naïve patients, changes in HbA_{1c} levels from baseline were + 0.6 for the placebo arm compared with - 0.8, - 0.6, and - 1.9 for the 15-mg, 30-mg, and 45-mg Actos arms, respectively. Changes in FBG levels from baseline were + 16 for the placebo arm compared with - 37, - 41, and - 64 for the 15-mg, 30-mg, and 45-mg Actos arms, respectively. Potential adverse reactions associated with Actos include upper respiratory tract infection, headache, sinusitis, and myalgia. The recommended dose of Actos is 15 mg or 30 mg once daily, up to a maximum of 45 mg once daily.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Deidre Yoder, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.